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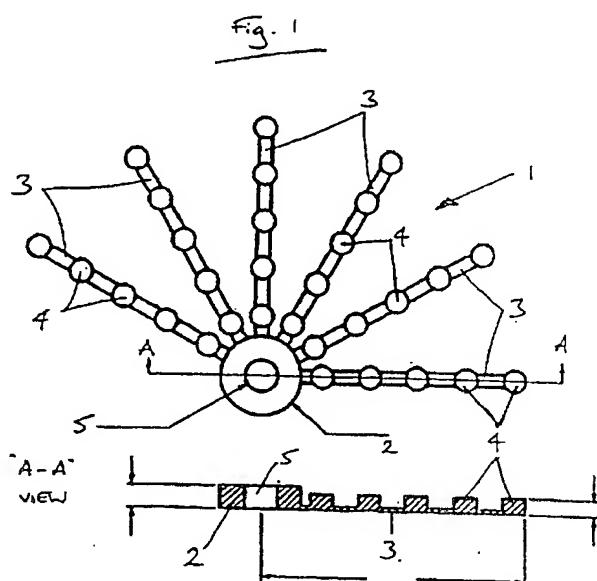
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(54) Abstract Title

Indicating tag to show the number of uses a piece of apparatus has undergone

(57) An indicating tag 1 adapted to be secured to an apparatus for indicating the number of uses the apparatus has undergone comprises a body portion 2 from which one or more limbs 3 extend, each limb having one or more elements 4 thereon. One element may be removed from the tag following each use of the apparatus to which the tag is secured. The tag may comprise N elements, N being the number of permitted uses of the apparatus. The apparatus may be a surgical apparatus and the uses sterilisation cycles, in which case the tag may be made from a mouldable material which retains its shape when subjected to a sterilisation cycle, e.g. a thermoplastic elastomer or silicon rubber.



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Fig. 1

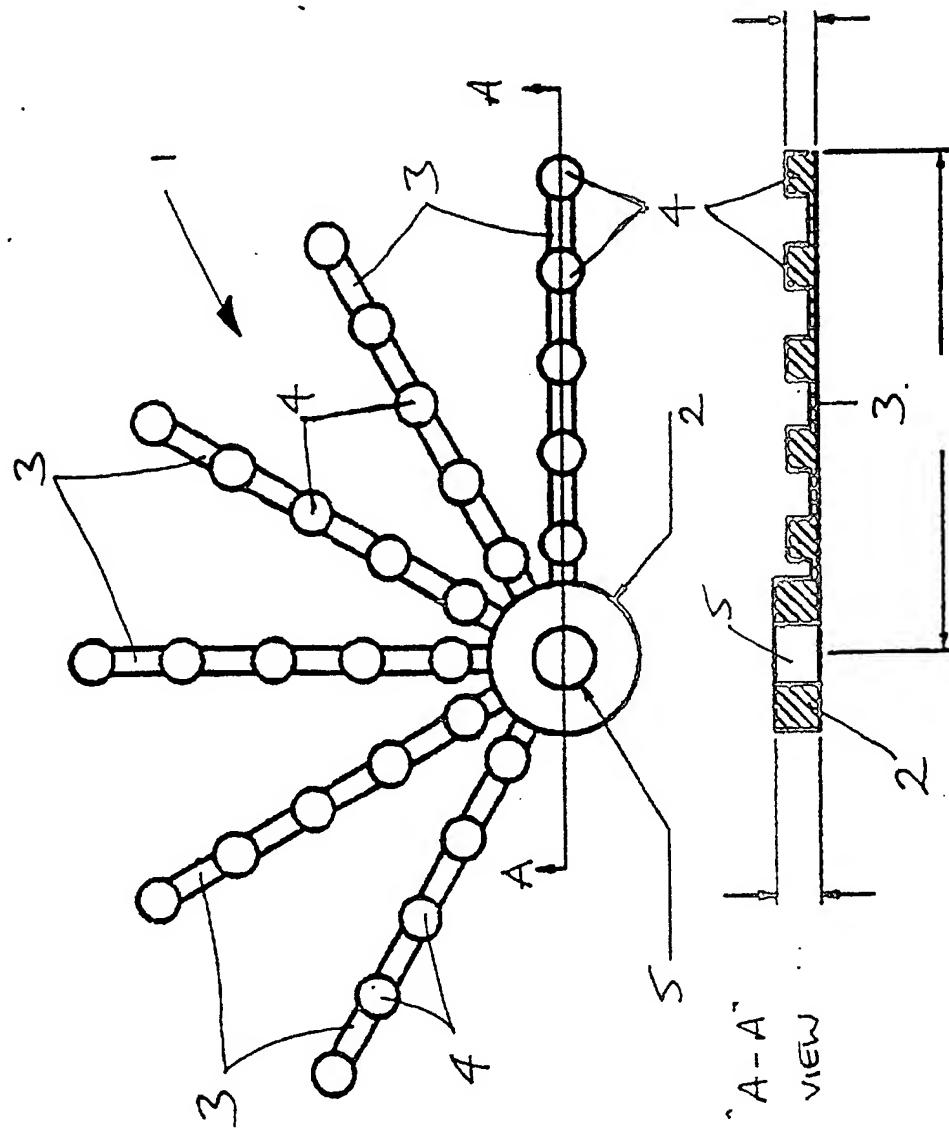
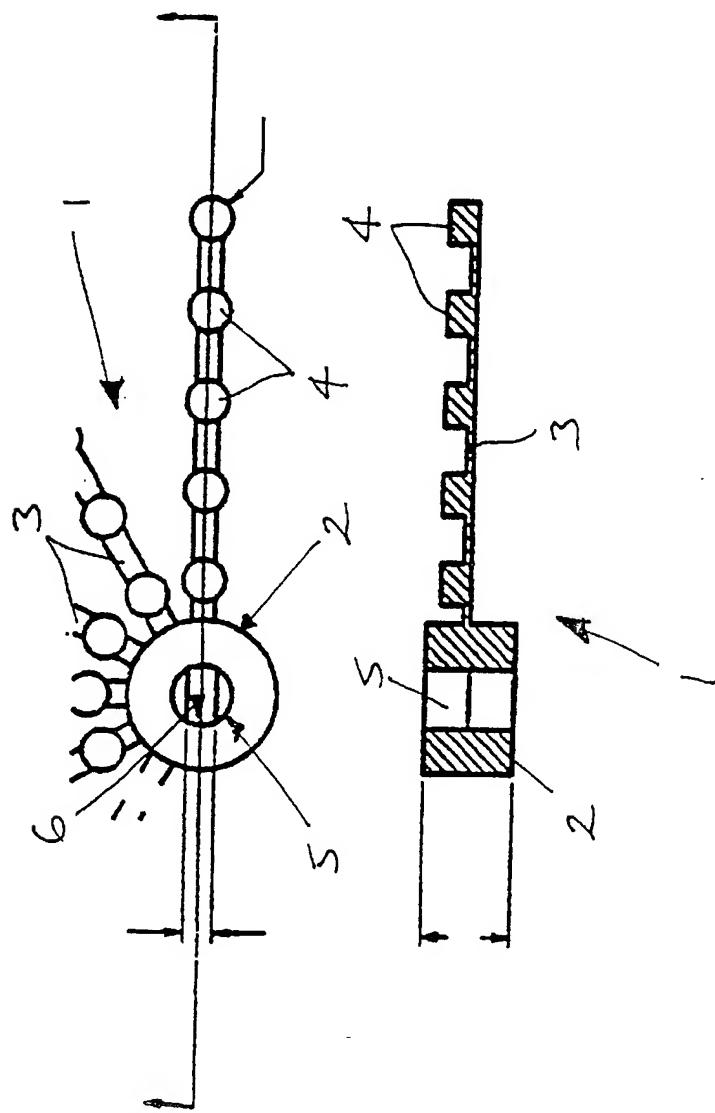


Fig. 2



1 **STERILISATION CYCLE INDICATOR TAG**

2

3 The present invention relates to indication means for
4 use in monitoring cycles of treatment experienced by an
5 item of apparatus. In particular the present invention
6 relates to a tag for use in monitoring the number of
7 cycles of sterilisation treatment to which an item of
8 surgical apparatus is subjected.

9

10 In surgical operating theatres, electrical cables are
11 required for the powering of surgical and monitoring
12 equipment. In addition, high-frequency electrical
13 currents are required in a number of surgical
14 procedures in the surgical area of the theatre. One
15 such procedure is diathermy, where an electrical
16 current is used on a patient in order to produce
17 coagulation or necrosis of skin cells.

18

19 As with all equipment that is used in the surgical
20 area, the cables carrying these currents are required
21 to be sterile. Thus, after each use, the cables are
22 put through a sterilisation cycle in order to be
23 sterilised. For sterilisation, the sterilising cycles
24 commonly use either high energy ionising radiation,
25 steam autoclaving, or ethylene oxide exposure on the

1 cables. With any of these sterilisation cycles,
2 degradation of the cable will occur. Thus, the cables
3 may only be used for a certain number of cycles before
4 they fail, and a new cable is required.

5

6 However, using a cable to failure is a hazardous
7 practice, as it is common for the person using the
8 cable to receive a painful burn from the spark produced
9 when the cable fails. As a precaution, therefore,
10 cable manufacturers only recommend that their cables be
11 used for a particular number of cycles before they
12 should be replaced. In practice, however, it has so
13 far proved difficult and inconvenient for surgical
14 staff to record each cycle that a cable is put through.

15

16 A number of methods have been suggested for keeping
17 track of the number of cycles that cables have been
18 through. In theory, a straightforward method would be
19 to assign each individual cable a code number in the
20 manufacturing process. The surgical staff would then
21 note each time they sterilised a particular cable. In
22 practice, however, staff would find this hugely
23 impractical to record each cycle on a daily basis. A
24 simpler method would be to print a dot or mark on the
25 cable. This mark would then diminish after every cycle
26 until it disappeared entirely, and the cable would then
27 be thrown away. This method is particularly inexact,
28 as there would be no way of knowing the exact number of
29 cycles the cable had been through.

30

31 It is therefore the aim of the present invention to
32 provide a simple, straightforward, and practical
33 indication means that can show exactly how many times a
34 cable or other item of surgical apparatus has been
35 sterilised. Thus, the cable may be discarded after the
36 manufacturer's recommended number of cycles is reached

1 without any ambiguity, and without any risk of injury
2 to those who come into contact with the degraded
3 cables.

4
5 According to a first aspect of the present invention,
6 there is provided an indicating tag adapted to be
7 secured to an apparatus in which the number of uses of
8 said apparatus must be monitored, wherein said
9 indicating tag comprises a body portion and one or more
10 limbs extending from said body portion, each of said
11 limbs having one or more elements thereon, said
12 elements being arranged such that an element may be
13 removed from said tag following each use of the
14 apparatus to which the tag is secured.

15
16 Preferably, the apparatus is a surgical apparatus and
17 the use is a sterilisation cycle.

18
19 Preferably the tag has N elements where N is the number
20 of permitted uses of the apparatus.

21
22 Preferably the tag comprises a plurality of limbs.
23 Preferably each limb has a plurality of elements
24 thereon. Preferably each limb is an elongate member.
25 Preferably said elements comprise thickened portions of
26 said limb arranged longitudinally along said elongate
27 member.

28
29 Preferably, said limb comprises a substantially
30 cylindrical member having a first diameter or a flat
31 member having a first thickness. Preferably, each
32 element comprises a substantially spherical portion
33 having a second diameter greater than said first
34 diameter or thickness. Alternatively each element may
35 comprise a disc shaped portion or a block shaped
36 portion having an overall transverse dimension greater

1 than said first diameter or first thickness.

2

3 Preferably said tag is made from a mouldable material
4 which retains its physical shape when subjected to
5 sterilisation. Preferably, said tag is made from a
6 thermoplastic elastomer material such as Santoprene®.
7 Alternatively, said tag is made from silicon rubber.

8

9 Preferably, said tag further comprises fastening means
10 for attaching said tag to the apparatus. The fastening
11 means may comprise male and female cable tie members,
12 an aperture adapted to surround a portion of the
13 apparatus, or other suitable fastening means.

14

15 According to a second aspect of the present invention,
16 there is provided a method for counting the number of
17 uses of an apparatus, said method comprising attaching
18 a tag according to the first aspect of the present
19 invention to an apparatus,
20 wherein the tag has N elements where N is the number of
21 permitted uses of the apparatus, and
22 wherein one of the elements is removed from said tag
23 each time the apparatus is used, such that no elements
24 remain on the tag after N uses.

25

26 Preferred embodiments of the present invention will now
27 be described, by way of example only, with reference to
28 the following drawings, in which:

29

30 Figure 1 shows plan and cross-sectional views of a
31 first embodiment of the present invention.

32

33 Figure 2 shows plan and cross-sectional views of a
34 detail of a second embodiment of the present
35 invention.

36

1 Figure 1 shows an indicating tag 1 in accordance with
2 the present invention. The indicating tag 1 of Figure
3 1 is intended for use in conjunction with cables in
4 operating theatres, where said cables must be
5 sterilised after each use. As discussed above, the
6 cables degrade after each sterilisation cycle, and as a
7 precaution manufacturers recommend a maximum number of
8 cycles before the cable should be replaced.

9
10 The indicating tag 1 has a cylindrical body portion 2
11 from which extend a number of limbs 3, and
12 equidistantly spaced along the length of each limb 3
13 are a number of protruding portions or dimples 4. The
14 number of limbs 3 and the number of dimples 4 on each
15 limb 3 is dictated by the number of cycles that the
16 manufacturer of the cables recommends should not be
17 exceeded. For example, if it is recommended that a
18 cable should not be subjected to more than forty
19 sterilisation cycles, then eight limbs 3 with five
20 dimples 4 on each limb 3 would be provided around the
21 circumference of the cylindrical body 2.

22
23 The aim of the present invention is to provide very
24 simple means with which to monitor the number of cycles
25 that a piece of equipment - in this example, cables -
26 has been through. After each cycle, the operator who
27 has sterilised the cable simply takes a pair of
28 scissors or the like, and removes the outermost dimple
29 4 from one of the limbs 3. Alternatively the limbs may
30 be thin enough to allow a dimple to be removed by hand
31 by pulling the end dimple. This process is repeated
32 after each cycle until such time as there are no
33 dimples 4 or, as a consequence, limbs 3 remaining.
34 Once the final dimple 4 has been removed, this then
35 tells the operator that the cable has been sterilised
36 the recommended number of times, and that it should now

1 be discarded and replaced by a new cable.

2

3 Figure 1 shows an embodiment of the present invention
4 where the centre aperture 5 of the cylindrical body 2
5 is circular to accommodate a standard single cable.

6 Figure 2, however, shows a second embodiment of the
7 present invention wherein the indicating means 1 has a
8 modified centre aperture 5. The aperture 5 has been
9 modified into the shape of a slot 6, so that dual
10 cables can be accommodated and held securely by the
11 aperture 5.

12

13 In the preferred embodiments of the present invention,
14 the indicating means 1 is manufactured from the
15 thermoplastic elastomer Santoprene® and moulded in one
16 piece. Santoprene® is produced by Advanced Elastomer
17 Systems and has a wide variety of uses in the medical
18 products field. Santoprene® benefits from having the
19 same properties as a conventional thermoset rubber
20 allied to the easy processability of a thermoplastic.
21 In addition, as Santoprene® is totally synthetic and
22 not derived from natural rubber, it is free from the
23 problems associated with natural rubber in medical
24 applications, such as allergic reactions and the like.

25

26 Although Santoprene® is the preferred material from
27 which to produce the present invention, other materials
28 may be used. For example, silicon rubber shares
29 similar properties to Santoprene®.

30

31 Other modifications and improvements may be
32 incorporated without departing from the scope of the
33 present invention. For example, the present invention
34 need not only be used in conjunction with cables. As
35 well as other medical apparatus such as laryngeal
36 masks, for example, the present invention could be used

1 with any equipment in which the number of uses of said
2 equipment must be monitored. The means of attachment
3 may be a cable tie instead of an aperture. This would
4 enable the tag to be put on a cable after the end plugs
5 have been attached to the cable. Other means of
6 attachment are possible, such as riveting, bolting,
7 clamping, adhesives etc.

8
9 The shape of the tag is not limited to that shown in
10 the drawings. Although the drawings show disc shaped
11 protruding elements, these may be spheres, cuboid
12 blocks, rods or other polygonal shapes.

13
14 These and other modifications and improvements can be
15 incorporated without departing from the scope of the
16 invention.

1 **CLAIMS:**

2

3 1. An indicating tag adapted to be secured to an
4 apparatus in which the number of uses of said apparatus
5 must be monitored, wherein said indicating tag
6 comprises a body portion and one or more limbs
7 extending from said body portion, each of said limbs
8 having one or more elements thereon, said elements
9 being arranged such that an element may be removed from
10 said tag following each use of the apparatus to which
11 the tag is secured.

12

13 2. An indication tag according to Claim 1, wherein
14 said tag has N elements where N is the number of
15 permitted uses of the apparatus.

16

17 3. An indicating tag according to either Claim 1 or
18 Claim 2, wherein said tag comprises a plurality of
19 limbs.

20

21 4. An indicating tag according to Claim 3, wherein
22 each of said plurality of limbs has a plurality of
23 elements thereon.

24

25 5. An indicating tag according to any preceding
26 claim, wherein each of said one or more limbs is an
27 elongate member.

28

29 6. An indicating tag according to Claim 5, wherein
30 each of said one or more elements comprise thickened
31 portions of said limb arranged longitudinally along
32 said elongate member.

33

34 7. An indicating tag according to any preceding
35 claim, wherein said apparatus is a surgical apparatus
36 and the use is a sterilisation cycle.

1 8. An indicating tag according to Claim 7, wherein
2 said tag is made from a mouldable material which
3 retains its physical shape when subjected to the
4 sterilisation cycle.

5

6 9. An indicating tag according to Claim 8, wherein
7 said tag is made from a thermoplastic elastomer
8 material.

9

10 10. An indicating tag according to Claim 8, wherein
11 said tag is made from silicon rubber.

12

13 11. An indicating tag according to any preceding
14 claim, wherein said tag further comprises fastening
15 means for attaching said tag to the apparatus.

16

17 12. An indicating tag according to Claim 11, wherein
18 said fastening means comprises male and female cable
19 tie members.

20

21 13. An indicating tag according to Claim 11, wherein
22 said fastening means comprises an aperture adapted to
23 surround a portion of the apparatus.

24

25 14. A method for counting the number of uses of an
26 apparatus, said method comprising attaching a tag
27 according to any of Claims 1 to 13 to an apparatus,
28 wherein the tag has N elements where N is the number of
29 permitted uses of the apparatus, and
30 wherein one of the elements is removed from said tag
31 each time the apparatus is used, such that no elements
32 remain on the tag after N uses.

33

34 15. An indicating tag as substantially hereinbefore
35 described and illustrated in the accompanying drawings.

36

- 1 16. A method for counting the number of uses of an
- 2 apparatus as substantially hereinbefore described.



Application No: GB 9921450.4
Claims searched: 1-16

Examiner: Annabel Ovens
Date of search: 4 February 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): G5C (CAD, CAX, CBL, CBM, CFX), A5G (GAA)

Int Cl (Ed.7): A61L (2/26), G09F (3/00, 3/02, 19/00)

Other: Online: PAJ, EPODOC, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X, Y	WO 97/04644 (SERIEYS) see page 2 lines 13-18 and 27-31, page 4 lines 5-6 and Fig.	X: 1, 2, 5, 11 and 14 Y: 6
X	WO 95/14375 (LOGAN) see page 1 lines 16-20 and 28-33, page 2 lines 22-27 and Fig.	1, 2 and 11, 12 and 14
Y	US 3556291 (SEBRING) see column 2 lines 53-58 and Figs. 4 and 5	6

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.